protein is remarkably similar to kandaptin, such is not persuasive since Applicants disclose neither the level of similarity, nor how such was determined. Initially, in response, Applicants are frankly unaware of any basis in the law for the Examiner's requirement. Rather, without a reason to doubt the truth of statements made [1/], Applicants statements are to be accepted. In re Wright, 27 USPQ2d 1510 (Fed. Cir. 1993). Accordingly, respectfully submitted, such is believed to be immaterial to the inquiry under 35 U.S.C. §101.

In any event, however, Applicants wish to point out that the present invention does satisfy 35 U.S.C. §101. To violate 101, the claims "must be totally incapable of achieving a useful result." Brooktree Corp. v. Advanced Micro Devices, Inc., 24 USPQ 2d 1401, 1412 (Fed. Cir. 1992). In this regard, the Patent Office issued Revised Interim Utility Guidelines at 64 Fed. Reg. 71440-42 on December 21, 1999. According to the Revised Guidelines, any single credible assertion of specific and substantial utility for any claimed invention satisfies the utility requirement. Id at 71441. The Revised Guidelines were promulgated in response to concerns of asserted utilities so insubstantial as not to support patentability, "such as the use of a complex invention as landfill." Id. Applicants' burden under 35 U.S.C. §101 is only to aver a utility that those of ordinary skill would more likely than not consider credible.

Put another way, according to the Revised Guidelines, the Examiner must establish a *prima facie* showing that one skilled in the art would most likely not consider credible any specific and substantial utility asserted by Applicant. Id at 71442. The *prima*

1/ Such "reason to doubt" is where the statements are without credibility on their face, e.g., where Applicants aver they enable perpetual motion or immortal life, etc. However, there is no provision in the law for requiring Applicants to provide the bases of their considered, credible conclusions.

facie showing for each utility averred, as well as for each utility that would be apparent, must contain the following elements:

1. An explanation that clearly sets forth the reasoning used;

2. Support for the factual findings relied upon in reaching this conclusion; and

3. An evaluation of all relevant evidence of record.

The Revised Guidelines emphasize the importance of documentary evidence establishing one of ordinary skill would disbelieve any utility described in the specification for the invention. A *prima facie* showing should provide scientific or technical journals, excerpts from treatices or books, or U.S. or foreign patents to support the factual basis. Id.

There was no such documentary evidence provided by the Examiner in support for his factual findings.[2/] Indeed, not only is there a total lacking of documentary evidence, but the Examiner's factual finding is, respectfully submitted, irrelevant.

While Applicants do not disagree with the Examiner's statement that a single change can alter activity, it is plain those of ordinary skill do in fact expect similarity of activity.[3/] That is to say, the skilled artisan is surprised to find that there is no activity despite a close similarity in sequence.[4/] This is all the law requires, e.g., that those of

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2/ That "a percentage similarity of less than 100% is not deemed to reasonably support to one skilled in the art whether the biochemical activity of the claimed subject matter would be the same as that of such a similar known biomolecule. It is known for nucleic acids as well as proteins, for example, that even a single nucleotide or amino acid charge or mutation can destroy the function of the biomolecule."

3/ If it will be helpful, in this regard, to complete the record, Applicants will be happy to supply a suitable Declaration under Rule 132.

4/ In fact, the Patent Office has recognized this state of the art by issuing from 1996 to (continued...)

ordinary skill would more likely than not consider Applicants' assertions to be credible. Accordingly, there is no adequate basis for the rejection under Section 101 and this basis of rejection too is plainly overcome and should be withdrawn. In any event, it is also clear as explained below that Applicants do meet their burden of showing a credible, specific and substantial utility.

The nucleotide is a full-length clone that encodes a secreted protein isolated from human fetal brain. Specification page 197, lines 23-29. As noted, Applicants believe the protein has sequences which are sufficiently similar to AF035526, R18277, R47371 and Z40133, especially AF 035526 and Z22181 that those of ordinary skill expect it to share activity with these mouse kandaptin proteins. Specification page 198, lines 7-17 and 19-20.

Applicants have particularly stated the resemblance of the present invention to specific proteins of well-characterized activity and have set forth their belief that the present invention would share at least a part of that activity. For that reason alone, the present invention plainly satisfies 35 U.S.C. §101.

Moreover, even if arguendo those of ordinary skill would for some reason be more than likely to disregard Applicants' statements, the present invention plainly has specific and substantial utility as research reagent for better characterizing the nature of the prior art proteins, e.g., AF035526 and Z22181. The Examiner has made nothing documentary of record evidencing the contrary, and the "support for the factual findings

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[4/](...continued)
date more than 120 patents which contain the claim language "polynucleotide which hybridizes."

relied upon in reaching [his] conclusion" do not address all of Applicants assertions and apparent utilities, as required by the Revised Guidelines.

Claims 1-5, 8 and 14-49 are also rejected under 35 U.S.C. §112 first paragraph. In support of this rejection, the Examiner states that because the invention is not supported by a substantial asserted utility, one of ordinary skill would not know how to use it. However, as seen explained above, the present invention is supported by a specific and substantial utility. Moreover, one skilled in this art would readily understand how to make and use the present invention, at the very least, for better characterizing the prior art kandaptin proteins simply from its close relationship to those sequences.

The Examiner further continues to object to Applicants' use of the term "isolated" in the claims, apparently because their usage is thought to be repugnant to its accepted meaning in the art.[5/] In that regard, "isolated polynucleotide" is plainly a term accepted in this as evidenced by the issuance[6/] of more than 1065 patents containing that language. However, the Examiner has made no argument as to why or how Applicants' usage is purportedly incorrect or differs from the common meaning. Nonetheless, solely in order to reduce the issues and expedite the prosecution of this application, the claims have been amended to specify that the coding sequence of the polynucleotide consists essentially of SEQ ID NO:21. Accordingly, this rejection should now be overcome and withdrawal thereof is earnestly solicited.

5/ This could be the only possible basis for objection since the term is obviously well-known to the skilled artisan.

6/ As shown by a cursory search of the USPTO website for patents with claims containing that term issued just from 1996 to date.

In this regard, the Examiner also mentioned (in connection with the discussion under the 35 U.S.C. §112, first paragraph rejection)

> [t]he claimed polynucleotides also continue to read on undescribed cDNA sequences found in complete cDNA sequences such as that disclosed by GenBank Version No. AK001486.1 (Isogai et al.), as discussed in the previous Office Action.

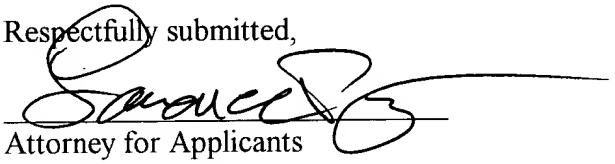
Although this statement is respectfully traversed, "comprising" has been changed to --consisting of-- as discussed previously, in order to reduce the issues most expediently. Accordingly, this basis of the rejection (or indeed, any rejection under 35 U.S.C. §§102 or 103) is therefore overcome as well.

In view of the above amendments and remarks, Applicants submit that all of the Examiner's concerns are now overcome and the claims are now in allowable condition. Accordingly, reconsideration and allowance of this application is earnestly solicited.

Claims 1-5, 8 and 14-19 remain presented for continued prosecution.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,



Attorney for Applicants
Lawrence S. Perry
Registration No. 31,865

FITZPATRICK, CELLA, HARPER & SCINTO
30 Rockefeller Plaza
New York, New York 10112-3801
Facsimile: (212) 218-2200
NY_MAIN 243762 v1

VERSION WITH MARKINGS TO SHOW CHANGES MADE TO CLAIMS

1. (Twice Amended) An isolated polynucleotide comprising a coding sequence consisting of the nucleotide sequence of SEQ ID NO: 21.

8. (Twice Amended) An isolated polynucleotide comprising a coding sequence consisting of the cDNA insert of clone er311_20 deposited under accession number ATCC 98781.

14. (Amended) An isolated polynucleotide comprising a coding sequence consisting of the nucleotide sequence of SEQ ID NO:21 from nucleotide 8 to nucleotide 2008.

15. (Amended) An isolated polynucleotide [comprising a nucleotide] coding sequence that encodes a protein [comprising] consisting of the amino acid sequence of SEQ ID NO:22.

16. (Amended) An isolated polynucleotide that hybridizes under conditions at least as stringent as 1X SSC at 65 degrees C, or 1X SSC at 42 degrees C with 50% formamide, followed by washing in 0.3X SSC at 65 degrees C, to a complement of the polynucleotide [set forth as SEQ ID NO:21] of claim 1, wherein said polynucleotide encodes a polypeptide having a kanadaptin activity.

17. (Amended) An isolated polynucleotide that hybridizes under conditions at least as stringent as 1X SSC at 67 degrees C, or 1X SSC at 45 degrees C with 50% formamide, followed by washing in 0.3X SSC at 67 degrees C, to a complement of the polynucleotide [set forth as SEQ ID NO:21] of claim 1, wherein said polynucleotide encodes a polypeptide having a kanadaptin activity.

18. (Amended) An isolated polynucleotide having at least 90% sequence identity to the polynucleotide [set forth as SEQ ID NO:21] of claim 1, wherein said polynucleotide encodes a polypeptide having a kanadaptin activity.

19. (Amended) An isolated polynucleotide having at least 95% sequence identity to the polynucleotide [set forth as SEQ ID NO:21] of claim 1, wherein said polynucleotide encodes a polypeptide having a kanadaptin activity.